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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,726	08/04/2003	Lee Weng	THRSP0004-0002	5582

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
MANTIS MERCADER, ELENI M	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,726	WENG ET AL.	
	Examiner	Art Unit	
	Eleni Mantis Mercader	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 10 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No.6,626,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are constitute a broadening in scope of the patented claim and therefore anticipated by the claims. Note that application of the ultrasonic therapy can be at any area of interest including fibroids.

3. Claims 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No.6,626,855 in view of Chapelon et al.'526 and Ribault et al.'639.

Chapelon et al.'526 teach that pre-heating lowers the cavitation threshold providing a more effective treatment at a localized area of interest by limiting the treatment duration and avoiding spreading of the heat (see col. 5, lines 59-65 and col. 10, lines 35-43). Furthermore, Ribault et al.'639 teach that hyperthermia or heating of the tissues other than HIFU is performed

at about 45 degrees C, which is about 50 degrees C as disclosed by the current invention (see col. 1, lines 17-30). Therefore it would have been obvious to one skilled in the art that while not expressly stated the current invention applies hyperthermia at about 50 degrees C.

It would have been obvious to one skilled in the art at the time that the invention was made that hyperthermia occurs at about 50 degrees C and leads to a more efficient treatment as taught by Chapelon et al.'526 and Ribault et al.'639 as stated by their teachings.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Vaezy et al.'867 (US Patent No. 6,425,867).

Vaezy et al.'867 teach a method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of:

a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)),

b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood

supply to the uterine fibroid (see col. 16, lines 19-20; referring to treatment of fibroid and col. 16, lines 50-58; referring to necrosing tissue at a plurality of selected locations by causing lesions to the blood vessels).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaezy et al.'867 in view of Chapelon et al.'526 (US Patent No. 5,601,526).

Vaezy et al.'867 teach an efficient heating method using high intensity ultrasound energy comprising the following steps:

providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)); and

determining a tissue treatment zone (an indicated in Figure 6, and col. 16, lines 50-58; there is a treatment zone of one or more 112a lesion areas).

Vaezy et al.'867 do not teach energizing the ultrasound transducer to cause pre-focal heating at the tissue treatment zone and re-energizing the ultrasound transducer to cause necrosis at the tissue treatment zone.

In the same field of endeavor, Chapelon et al.'526 teach energizing the ultrasound transducer to cause pre-focal heating at the tissue treatment zone and re-energizing the

ultrasound transducer to cause necrosis at the tissue treatment zone (see col. 7, lines 17-55 and col. 10, lines 35-63; referring to pre-heating of the area of interest with thermal waves and subsequent treatment at the focal region with focal cavitation waves in order to necrose the tissue).

It would have been obvious to one skilled in the art at the time the invention was made to have modified Vaezy et al.'867 and incorporated the teachings of Chapelon et al.'526 in the treatment of fibroids because as taught by Chapelon et al.'526 this lowers the cavitation threshold providing a more effective treatment at a localized area of interest by limiting the treatment duration and avoiding spreading of the heat (see col. 5, lines 59-65 and col. 10, lines 35-43).

8. Claims 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaezy et al.'867 in view of Chapelon et al.'526 as applied to claim 11 above, and further in view of Ribault et al.'639 (US Patent No. 6,488,639).

Vaezy et al.'867 in view of Chapelon et al.'526 teach all the steps as enumerated above except for the explicit recitation that pre-focal heating of the tissues causes temperature of the tissue to increase to about 50 degrees C.

Ribault et al.'639 teach that hyperthermia or heating of the tissues other than HIFU is performed at about 45 degrees C, which is about 50 degrees C as disclosed by the current invention (see col. 1, lines 17-30).

It would have been obvious tone skilled in the art at the time that the invention was made that the hyperthermia temperature is about 50 degrees C as expressly stated by Ribault et al.'639.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM